

DOCKET NUMBER: 64230-00005USD2
PATENT

REMARKS

Status of the Claims

Claims 33 and 34 are pending. Claims 33 and 34 currently stand rejected. Claims 33 and 34 are identical to issued claims 1 and 33, respectively, of U.S. Patent No. 6,162,258 to Scarborough, *et al.* (the "Scarborough patent").

Summary of the Substance of Interview with the Examiner on October 28, 2004

Present were Examiners David Comstock and Eduardo Robert, as well as, Lloyd Wolfenbarger, Jr. (Inventor) and the undersigned. Claims 33 and 34 were discussed in view of cited art Livesey, *et al.* (U.S. 5,336,616) and Boyce, *et al.* (U.S. 5,899,939). No agreement was reached with respect to the claims. Differences between cryopreservation and freeze-drying were discussed. Plasticization effects of glycerol added to bone before lyophilization were discussed. Applicant argued that the processes taught by the references did not teach or suggest the claimed invention.

Amendment of the Specification

The amendment suggested by the Examiner to improve the clarity of the specification has been adopted. No new matter has been added in the specification.

Rejection of Claim 34 under 35 U.S.C. §102(b)

Claim 34, which is identical to claim 33 of the Scarborough patent, was rejected under 35 U.S.C. §102(b) as anticipated by Livesey, *et al.* (U.S. 5,336,616).

DOCKET NUMBER: 64230-00005USD2
PATENT

The Examiner contends that Livesey, *et al.* "disclose that it is known to contact bone for transplantation with glycerol, or other liquid organic preservation solution, and to freeze-dry (i.e., lyophilize) or cryopreserve the bone (see col. 3, lines 31-37 and 53-57)." Office Action at page 3.

Applicant respectfully disagrees with the Examiner. At col. 3 lines 31-37, it is taught that allogenic bone may be used fresh or may be cryopreserved with DMSO and/or glycerol, to maintain cellular components. Cryopreservation and lyophilization are not synonymous. (See attached definitions.) Cryopreservation means freezing at low temperatures, while lyophilization requires freezing at low temperatures, and then warming gradually under vacuum, so that water crystals sublime and the tissue is dehydrated. Livesey, *et al.* teaches that the viable cells of the cryopreserved tissues can cause an immune response upon transplantation, and the host can require immunosuppressive therapy.

At col. 3 lines 53-57, Livesey, *et al.* goes on to teach that alternative methods (see col. 3, line 50) to the cryopreservation techniques taught at lines 31-37 involve freeze-drying allogenic bone for transplantation. The freeze-drying is said to result in a graft which elicits no significant rejection response when compared to fresh or cryopreserved allogenic bone.

Cryopreservation with glycerol, and lyophilization are presented as alternative methods of treating bone. Livesey, *et al.* does not teach bone being lyophilized in the presence of glycerol or other "liquid organic preservation solution." Withdrawal of the rejection of claim 34 is respectfully requested.

DOCKET NUMBER: 64230-00005USD2
PATENT

Rejection of Claim 34 under 35 U.S.C. §102(e)

Claim 34, which is identical to claim 33 of the Scarborough patent, was rejected under 35 U.S.C. §102(e) as anticipated by Boyce, *et al.* (U.S. 5,899,939).

The Examiner asserts that Boyce, *et al.* discloses a monolithic bone implant contacted with a liquid organic agent, i.e., a type of polyethylene glycol that is freeze dried. Examiner cites col. 1 lines 6-17; col. 2 lines 9-15; col. 4 lines 20-24, 45-46, and 53-56; col. 5 lines 21-29; and col. 6 lines 8-13, 45-46 and 51-52. See Office Action at page 3.

At col. 1 lines 6-17, Boyce, *et al.* presents the technical field of the invention as relating to bone-derived implants, and in particular to implants made of two or more layers, at least one of which is fully mineralized or partially demineralized. Boyce, *et al.* teaches an object of the invention is a bone implant having a network of pores or channels, among other types of spaces, that permit and encourage bone growth and healing that can provide a means for incorporating at least one bone healing substance. (See col. 2 lines 9-15.) Boyce, *et al.* further teaches that layers of the bone implant can comprise layers formed from materials other than bone. Pores or channels, among other spaces can be partially or completely filled with one or more substances that promote or accelerate bone growth or healing. (See col. 4 lines 20-24, 45-46, and col. 4 lines 53-56.) It is taught by Boyce, *et al.* that "permeation enhancers" such as fatty acid esters are among the substances that promote bone growth and healing (col. 5 lines 21-29). Among the substances listed as possible growth enhancers, along with the fatty acid esters, are living cells and blood. At least these components of the list would generally not be suitable for lyophilization. The passage does not indicate subsequent lyophilization of implants treated with fatty acid esters.

DOCKET NUMBER: 64230-00005USD2
PATENT

The only reference to freeze-drying in the patent is in Example 1, col. 6 lines 48-52. However, Example 1 does not teach contacting the bone with a liquid organic material that penetrates and remains in the bone during and after lyophilization. Furthermore, in Example 1 the bone is "continuously wetted with water," and then freeze-dried. By definition of freeze-drying the water would be removed from the implant, and the presence of a liquid organic material in the implant after freeze-drying is not taught. Withdrawal of the rejection of claim 34 is respectfully requested.

Rejection of Claim 33 under 35 U.S.C. §103(a)

Claim 33, which is identical to claim 1 of the Scarborough patent, was rejected under 35 U.S.C. §103(a) as being unpatentable over Livesey, *et al.* in view of Morse, *et al.* (U.S. 5,333,626). The Examiner asserts Livesey, *et al.*, teaches the claimed invention except that it does not explicitly disclose packaging of the implant, and that Morse, *et al.* discloses a similar invention and its packaging. Livesey, *et al.*, and Morse, *et al.* taken alone or together do not teach every element of the claimed invention as discussed above. Specifically, the references do not teach contacting bone with a liquid organic material that penetrates and remains in the bone during a subsequent lyophilization step.

Claim 33, which, as stated above, is identical to claim 1 of the Scarborough patent, was also rejected under 35 U.S.C. §103(a) as being unpatentable over Boyce, *et al.* in view of Morse, *et al.* The Examiner asserts Boyce, *et al.*, teaches the claimed invention except that it does not explicitly disclose packaging the implant. Boyce, *et al.*, and Morse, *et al.* taken alone or together do not teach every element of the claimed invention. See the discussion above. Specifically, the

DOCKET NUMBER: 64230-00005USD2
PATENT

references do not teach contacting bone with a liquid organic material that penetrates and remains in the bone during a subsequent lyophilization step.

Withdrawal of the rejection of claim 33 is respectfully requested.

Conclusion

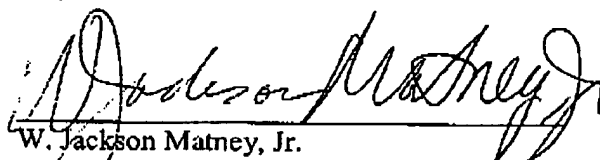
In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response; please charge any deficiency in fees or credit any overpayments to Deposit Account No. 10-0447 (64230-00005USD2).

Respectfully submitted,

JENKENS & GILCHRIST
A Professional Corporation


W. Jackson Matney, Jr.
Reg. No. 39,292

Date: Nov 15, 2004
Jenkins & Gilchrist, P.C.
901 15th Street, N.W., Suite 900
Washington, DC 20005
(202) 326-1500
(202) 326-1555 (fax)